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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jan Weber

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

01/30/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/759,605	<b>Applicant(s)</b> WEBER ET AL.	
	<b>Examiner</b> Brian E. Pellegrino	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-33 is/are pending in the application.
- 4a) Of the above claim(s) 6,8,12,14-20,23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9,10,13,21,22 and 25-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/08 has been entered.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,7,9,13,26,27,30 are rejected under 35 U.S.C. 102(e) as being anticipated by Alt (2004/0039438). Fig. 2 shows an implant body **30** having a first surface covered with a catalyst of metal material **32**, paragraph 32. Coeckelberghs et al. (4752461) teach (col. 5, lines 41-53) that metal ions act as a catalyst to promote the decomposition of hydrogen peroxide to hydrogen and oxygen. Thus, the metal material of Alt is fully capable of being a catalyst as claimed. It can also be seen (Fig. 2) that the catalyst layer of material is covered with a "filter" layer **40** on the porous material **33** and the implant. Alt discloses (paragraph 38) the filter layer has "pores" and since the porous layer it covers has dimensions or pore sizes (paragraph 31) of a microporous

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size, it retards white and red blood cells. Regarding claim 7, the catalyst comprises a therapeutic **43**. With respect to claim 26, Alt discloses the catalyst metal can be platinum and can be previously treated, paragraph 32. Regarding claim 30, Alt discloses the base layer is a non-polymer, paragraph 31.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4,5,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt (2004/39438). Alt is explained supra. However, Alt does not explicitly recite to cover the entire surface of the implant with the catalyst and filter or that regions of high strain when the stent is expanded are not covered. Because the interstices of the outer layers on the stent are used for therapeutic material, it would have been obvious to one of ordinary skill in the art to cover the entire surface with the catalyst and filter material such that it holds more drug material, thus producing predictable results of being able to deliver more therapeutic material to the treatment site. With respect to claim 25 and its limitation of the covering on low strain regions when expanded and not high strain, it is common sense that the more material on an object that is expanding has to exert more force and thus more strain results in that area or region. Therefore it would have been obvious to one of ordinary skill in the art to use less filter material over the high strain regions such that it does not compromise the stent device. Such a modification provides predictable results.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt (2004/39438) in view of Alt (6217607). Alt is explained supra. However, Alt does not explicitly recite the porous material is titanium oxide. Alt '607 teaches that as an alternative to the porous iridium oxide, one can use titanium oxide, col. 13. It would have been obvious to one of ordinary skill in the art to substitute porous oxide materials and use titanium oxide as taught by Alt '607 with the stent of Alt '39438 since such a modification only involves routine skill and yields predictable results.

Claims 21,22,28,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt (2004/0039438) in view of Smalley et al. (2002/85968). Alt is explained supra. Alt does disclose the filter material can comprise iridium oxide, paragraph 37. However, Alt fails to disclose alternative filter material or coverings for the composite stent. Smalley et al. teach the use of catalysts with carbon nanotubes or bucky paper coated onto to composites including implants and prostheses, paragraphs 121,276. Smalley also teaches that the bucky paper is useful in supporting catalysts on devices (paragraph 126) and to provide a composite device resisting delamination, paragraph 14. Smalley additionally teaches the bucky paper can be used with oxides, paragraphs 94,166,268. Smalley also teaches that polymers can be applied to enclose the composite material and provide the bulk or support for the body framework, paragraphs 257,259. It would have been obvious to one of ordinary skill in the art to incorporate bucky paper and a polymer matrix as taught by Smalley et al. with the stent of Alt such that it improves the adherence of the layers formed on the stent material and provide a supportive device that will not collapse or degrade.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trozera (6475233) in view of Alt et al. (2004/0039438). Trozera shows (Figs. 6a-8c) different strut patterns for stents having a tapered cross-section relative to the longitudinal axis of the stent. Trozera also discloses the stent is expandable, col. 9, lines 26,30. However, Trozera fails to disclose the use of a catalyst and filter layer. Alt is explained supra. Alt discloses the outer coating layer or oxide aids in reducing inflammation, col. 10, lines 41-47. It would have been obvious to one of ordinary skill in the art to incorporate the catalyst and filter material on the stent as taught by such that the stent of Trozera can provide a limited inflammatory response when implanted.

### ***Response to Arguments***

Applicant's arguments filed 11/10/08 have been fully considered but they are not persuasive. Applicant argues that the stent of Alt '438 does not contain a filter layer that is porous. However, the Examiner respectfully disagrees since Alt clearly discloses that the covering layer or "filter" is not intended to entirely cap or cover the inner layer and thus it thus can be understood that it is then porous and acts as a filter, see paragraphs 31,37,38. The dimensions of the pores are clearly capable of retarding white and red blood cells as claimed since these are dimensions of ranges as disclosed in Applicant's specification.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

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USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In reviewing the obviousness rejections, the Applicant only disputed Alt '438 did not have the porous filter. However, since the Examiner established one is present, the arguments regarding the obviousness rejections are moot.

Applicant's arguments with respect to claim 31 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700

/Brian E Pellegrino/

Primary Examiner, Art Unit 3738